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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,607	10/07/2005	Michael Sturzl	0147-0265PUS1	3489

2292 7590 11/29/2007

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EXAMINER	
DANG, IAN D	

ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
11/29/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/537,607	STURZL ET AL.	
	Examiner	Art Unit	
	Ian Dang	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *PTO-90C,Revised Notice to Comply*.

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10537607	10/7/2005	STURZL ET AL.	0147-0265PUS1

BIRCH STEWART KOLASCH & BIRCH
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FALLS CHURCH, VA 22040-0747

EXAMINER
Ian Dang

ART UNIT	PAPER
1647	20071115

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

The CRF and paper copy submitted 09/26/2007 were received by the Office. However, they do not comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) because the line <213> response is invalid: per Sequence Rules, the only valid responses are: the Genus species of the organism, "Artificial Sequence," or "Unknown." "Artificial Sequence" and "Unknown" require explanation in the <220>-<223> section. It is noted that Applicant has listed "synthetic sequence" in line <213>.

Since the reply appears to be bona fide attempt to comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825), applicant is given a TIME PERIOD of THREE (3) MONTHS from the mailing date of this communication within which to correct the deficiency so as to comply with the sequence rules (37 CFR 1.821 - 1.825) in order to avoid abandonment of the application under 37 CFR 1.821(g). EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a). In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ian Dang whose telephone number is (571) 272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bridget E Bunner/
Primary Examiner, Art Unit 1647

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 26 September 2007 has been entered in full. Claims 1-13 have been amended and claims 16-25 have been added.

Claims 1-25 are pending and under examination.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825). See sequence compliance letter attached to the instant Office Action.

Claim Objections

Applicant's amendments made to claims 2, 10, and 11 filed on 10/26/2007 have overcome the objection of claims 2, 10, and 11 made in the last Office action. The objection of claims 2, 10, and 11 has been withdrawn.

Rejection Withdrawn

35 USC § 102

Applicant's response and arguments filed on 02/26/2007 have overcome the rejection of claims 1, 4, and 9-13 under 35 USC 102(b). The reference by Guenzi et al. (cited in the IDS

mailed 06/03/2005) does not teach an in vitro method identifying GBP-1 in the supernatant of a tissue culture, cell culture, or a body fluid. The rejection of claims 1-4, and 9-13 under 35 USC 102(b) has been withdrawn.

35 USC § 103

Applicant's response and arguments filed on 02/26/2007 have overcome the rejection of claim 14 under 35 USC 103(a). The rejection of claim 14 under 35 USC 103(a) has been withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 112 (Written Description)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 and the newly added claims 16-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis of this rejection is set forth for claims 1-15 at page 3 of the previous Office action of 26 March 2007.

Applicant's response and arguments filed on 9/26/2007 have been fully considered but they are not persuasive.

Applicant's claim amendments have been fully considered but are not found persuasive. Although Applicants have overcome the rejection under 35 USC 112, First paragraph (Written Description) regarding tissue sample, a body fluid, the proteins, a surface, and specific binding, an epitope, a system emitting signal, an enzyme, a peptide, a polypeptide, antibody, low molecular substance, the rejection under 35 USC 112, First paragraph (Written Description) is maintained for GBP-1 fragments and receptor.

At page 11 of the response, Applicant argues that while there may conceptually and theoretically be a near infinite number of GBP-1 fragments in the supernatants of tissues, body fluids and cell cultures, the fact of the matter is that the identification and quantification of GBP-1 in the supernatants of tissue samples, body fluids and cell cultures in full-length form or in the form of a manageable number of fragments is disclosed for the first time by the present Specification.

In addition, Applicant alleges that the amended claims are method claims directed to identifying, detecting and/or quantifying GBP-1 and GBP-1 fragments in the supernatants of tissues, body fluids and cell cultures. The claims are therefore restricted to full length GBP-1 and the manageable number of GBP-1 fragments that in fact exist in the supernatants of tissues, body fluids and cell cultures, as established by the above-reference teachings of the Specification.

Applicant's arguments have been fully considered but are not found persuasive. The amendments of claims 1-13 do not satisfy the written description requirement because the term "fragments" has been broadly interpreted by the Examiner as encompassing any variants, mutants, or deletions of the protein GBP-1.

To provide adequate written description and evidence of possession of claimed genus, the specification must provide efficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure/function correlation, and other identifying characteristics. Accordingly, in the absence of sufficient recitation of distinguishing structural/physical and identifying characteristics, the specification does not provide adequate written description of the claimed genus.

The claims of the instant application recite the phrase “a fragment of GPB-1” without any sufficient recitation of distinguishing structural/physical and identifying characteristics of the encompassed fragments. For instance, claim 1 recites “a fragment of GPB-1” but the claim does not disclose any identifying structural or functional characteristics for the fragments that can be identified in the claimed in vitro method. The specification only provides general teachings regarding fragments of GBP-1, but it does not provided any specific identifying structural characteristics so that one skilled in the art can correlate fragments of GBP-1 with the full length GBP-1 protein. For instance, the specification teaches that the term “fragment of GBP-1” describes both the fragments of this protein which have the biological activity of GBP-1 as described in the prior art and in this application, and fragments of the protein, which occur by cleavage, e.g. enzymatic cleavage, and which are indicative for inflammatory diseases (bottom of page 4 to top of page 5). However, the specification does not teach any fragments of GBP-1 or the detection of any GBP-1 fragments. At page 6, the specification does not provide sufficient teachings correlating the structure of the fragment of GBP-1 with its biological function, so that one skill in the art can identify the claimed GBP-1 of the instant application. In the absence of any identifying characteristics for the GBP-1 fragments, there may conceptually and

theoretically be a near infinite number of GBP-1 fragments in the supernatants of tissues, body fluids and cell cultures as acknowledged by Applicant at page 11 of the response.

Furthermore, there is no description of the conserved regions, which are critical to the structure and function of the genus claimed. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the fragments of GBP-1 encompassed by the claims. Thus, no identifying characteristics or properties of the instant fragments of GBP-1 are provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

At page 12 of the response, Applicants also point out that the Examiner does not cite any scientifically authoritative source which shows that the genus of GBP- 1 fragments in the supernatant of tissue samples, body fluids and cell cultures is in fact comprised of an unmanageable number of species; but engages in mere speculation regarding the conceptual and theoretical size of the number of GBP-1 fragments that comprise the genus. In doing so, the Examiner has failed to meet his evidentiary burden of proof in taking the position that the genus of GBP- 1 fragments is so broad relative to the scope of Specification's disclosure that a skilled artisan, upon reading the Specification, would question that Applicants had possession of the claimed genus.

Moreover, Applicant submits that the Examiner has failed to give sufficient evidentiary weight to the scientific disclosure of the working examples and Figures of the present

Specification, which factually establish that Applicants had possession of the claimed genus of GPB-1 and of GPB-1 fragments actually present in the supernatants of tissue cultures, cell cultures and body fluids. Rather, Applicant argues that the Examiner completely fails to take into account any of the scientific disclosure of the present Specification in imposing the written description rejection. Finally, Applicant argues the factual situation is further established by surveying the materials and methods and results sections of articles published in biological science journals at the time the present application was filed.

Applicant's arguments have been fully considered but are not found persuasive. Although Applicant has provided a definition for the term "fragment of GBP-1", the definition does not provide any identifying characteristics for the claimed fragments of GBP-1. The Examiner is relying upon the broadest interpretation encompassed by the term "a fragment of GBP-1" because the specification does not provide any specific functional or structural characteristics for the claimed GBP-1 fragments. Furthermore, the Examiner acknowledges that numerous articles published in JBC disclose protocols for detecting and quantifying proteins and proteins fragments, but Applicant has not satisfied the written description requirement for the GBP-1 fragments claimed in the instant application because the specification does not provide any structural or functional characteristics for the GBP-1 fragments. Finally, the current rejection is in compliance with the most currently-published version of the Written Description Guidelines.

In addition, Applicant has not satisfied the written description requirement for receptor. In the response filed on 9/26/2007, Applicant has not addressed the issues made for 'receptor" under 35 USC First, paragraph (Written Description).

As discussed at pages 3-5 of the previous Office Action of 3/26/07 and reiterated herein, Applicant recites the phrase “receptor” without any sufficient recitation of distinguishing structural/physical and identifying characteristics of the disclosed fragments. For instance, claims 1, 2, 11, 13, 16, and 25 recite the term “receptor” but the claims do not disclose any identifying structural or functional characteristics for the receptors that can be identified in the claimed in vitro method. The specification provides general teachings regarding receptor, but it does not provided any specific identifying structural characteristics so that one skilled in the art can correlate the claimed receptor with the any biological activity. For instance, the specification teaches that the term "specific binding" describes a specific interaction between a receptor and a ligand. One example of such a ligand is GBP- 1 or fragments of this protein. The specific interaction can be characterized with a "key-lock-principle". The receptor and the ligand have structures or motifs which fit with each other specifically, as e.g. an antigenic determinant (epitope) which interacts with the antigen binding site of an antibody. Accordingly, specific interaction is contrary to a more universal, more unspecific interaction (page 5, lines 11-17). In addition, the specification teaches that receptor is selected from the group consisting of peptides, polypeptides, low molecular substances, antibodies, or fragments or derivatives thereof and aptamers (page 9, lines 8-11).

However, the specification does not teach any identifying characteristic of the receptors claimed in this method. At pages 5 and 9, the specification does not provide sufficient teachings correlating the structure of the receptor with its biological function, so that one skill in the art can identify the claimed receptor of the instant application. Thus, no identifying characteristics or properties of the instant receptor are provided such that one of skill would be able to predictably identify the encompassed receptors as being identical to those instantly claimed. One of skill in

the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Claim Rejections - 35 USC § 112 (Enablement)

Claims 1-15 the newly added claims 16-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (1) the detection of GBP-1 protein in culture medium of IFN-γ stimulated HUVEC by ELISA and immunoprecipitation (2) the detection of circulating GBP-1 in the plasma of patients treated with IFN-α by ELISA and immunoprecipitation (3) the detection of circulating GBP-1 in the plasma of patients with systemic lupus erythematosus and arthritis by ELISA and immunoprecipitation (4) the detection of circulating GBP-1 in the liquor of patients with bacterial meningitis by ELISA and immunoprecipitation, does not reasonably provide enablement for an in-vitro method for identifying guanylate binding protein-1 in a sample comprising: (a) contacting a sample of the supernatant of a tissue culture, a sample of the supernatant of a cell culture or a sample of the supernatant of a body fluid with a first receptor which specifically binds guanylate binding protein-1 or a fragment of guanylate binding protein-1 and (b) detecting a specific binding of the receptor with guanylate binding protein-1 or a fragment of guanylate binding protein-1; and thereby identifying the presence of guanylate binding protein-1 in the supernatant of said tissue sample, supernatant of said cell culture sample or body fluid sample. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims. The basis of this rejection is set forth for claims 1-15 at page 5 of the previous Office action of 26 March 2007.

Applicant's response and arguments filed on 9/26/2007 have been fully considered but they are not persuasive.

The Nature of the Invention and the Breadth of the claims

Applicants submit that this assertion (a large number of GBP-1 protein fragments) is a factual mischaracterization of the claimed genus of GBP-1 protein fragments, as established above in Sections 3.1 and 3.2. For instance, the invention is a method for detecting GPB-1 in a sample. The invention relates to finding that GPB-1 is a secreted protein, and so the claims state the nature of the sample as a supernatant of a tissue culture, a supernatant of a cell culture or a body fluid.

Applicant's arguments have been fully considered but are not found persuasive. As disclosed supra, the specification provides general teachings regarding fragments of GBP-1, but it does not provided any specific identifying structural characteristics so that one skilled in the art can correlate fragments of GBP-1 with the full length GBP-1 protein. For instance, the specification teaches that the term "fragment of GBP-1" describes both the fragments of this protein which have the biological activity of GBP-1 as described in the prior art and in this application, and fragments of the protein, which occur by cleavage, e.g. enzymatic cleavage, and which are indicative for inflammatory diseases (bottom of page 4 to top of page 5). However, the specification does not teach any fragments of GBP-1 or the detection of any GBP-1 fragments. At page 6, the specification does not provide sufficient teachings correlating the structure of the fragment of GBP-1 with its biological function, so that one skill in the art can identify the claimed GBP-1 of the instant application.

In addition, the specification provides general teachings regarding receptor, but it does not provided any specific identifying structural characteristics so that one skilled in the art can

correlate the claimed receptor with the any biological activity. For instance, the specification teaches that the term "specific binding" describes a specific interaction between a receptor and a ligand. One example of such a ligand is GBP- 1 or fragments of this protein. The specific interaction can be characterized with a "key-lock-principle". The receptor and the ligand have structures or motifs which fit with each other specifically, as e.g. an antigenic determinant (epitope) which interacts with the antigen binding site of an antibody. Accordingly, specific interaction is contrary to a more universal, more unspecific interaction (page 5, lines 11-17). In addition, the specification teaches that receptor is selected from the group consisting of peptides, polypeptides, low molecular substances, antibodies, or fragments or derivatives thereof and aptamers (page 9, lines 8-11).

However, the specification does not teach any identifying characteristic of the receptors claimed in this method. At pages 5 and 9, the specification does not provide sufficient teachings correlating the structure of the receptor with its biological function, so that one skill in the art can identify the claimed receptor of the instant application.

The Unpredictability and State of the Art

At page 17 of the response, Applicants argue that "silence" in the art regarding "GBP-1 expression in other cell types" is not tantamount to unpredictability in the art, and the references cited by the Examiner actually teach successful detection of GBP- 1 in the intracellular spaces of a variety of cell types. In addition, Applicant argues that practicing a method for detecting GBP-1 or its fragments in culture supernatants or body fluids does not require knowledge of the cells from which they are produced. Indeed, such a method is useful for determining what cells produce GBP-1 by culturing them, if this is of interest. Finally, Applicant argues that the Examiner has not cited any specific, technical reasons supported by evidence that provide a reasonable basis to question the enablement of the presently claimed methods of identifying,

detecting and quantifying GBP-1 and GBP-1 fragments in the supernatants of tissue cultures, supernatants of cell cultures and body fluid samples.

Applicant's arguments have been fully considered but are not found persuasive. Although the references cited in the last Office action established the successful detection of full length for the GBP-1 polypeptide in intracellular spaces of numerous cell types (page 7 of the previous Office action, mailed 03/26/2007), the references do not teach any GBP-1 fragments that are detected in cells or secreted into the supernatant. In addition, the references do not disclose any fragments of GBP-1 having the same biological activity as the full length GBP-1.

One of skill in the art would not be enabled to make/use the claimed method because the state of the art does not disclose any fragments of GBP-1 and the specification does not provide any characteristics regarding the structural and functional features of the GBP-1 fragments that can be detected by the claimed method. Without such disclosure, the in vitro detection of GBP-1 fragments is unpredictable.

Working Examples

At page 18 of the response, Applicant argues that the Examiner appears to be mechanistically requiring that all claimed subject matter be supported by working examples, which violates well-established principles of patent law. Moreover, Applicants argue that the working examples of the Specification, together with the full disclosure of the Specification and knowledge and skills of a person of ordinary skill in the art, support the enablement of the full scope of the presently claimed GBP-1 and GBP-1 fragment detection methods.

Applicant's arguments have been fully considered but are not found persuasive. Although Applicant is not required to provide examples of all embodiments of a claimed invention, Applicants must provide sufficient supporting evidence for the claimed invention. The presence of a working example is one factor among the 8 Wands factors necessary to fulfill the

enablement requirement. However, with limited guidance and working examples in conjunction with consideration of the other 7 factors, Applicants have not provided sufficient evidence to make and use the claimed invention. The disclosure of the instant specification does not provide sufficient guidance to make/use the invention without undue experimentation.
In addition, while the specification provides numerous examples for the detection of full length GBP-1 (see Figure 9, page 14, or Figure 10, page 15), the specification does not provide any examples the detection of any GBP-1 fragments in the serum or in the liquor of patients with bacterial meningitis. Finally, the specification does not provide any working example for the step (a') labeling the proteins contained in the sample or (a'') labeling of the first receptor prior to contacting the first receptor prior to step (a).

Quantity of Experimentation Needed to Practice the Claimed invention

Applicants once again submit that the isolation, detection and quantification of proteins and protein fragments from supernatants of tissues, body fluids and cell cultures with receptors and antibodies that specifically bind epitopes through the use of signal emitting systems such as ELISA assays, western blots, immunohistochemistry, immunoflourescence, etc. are amongst the most fundamental, reliable and widely used scientific techniques available to artisans of ordinary skill in the field of the presently claimed invention.

Applicants again point out that 109 of the 142 articles (76%) published in the JBC issue dated December 20, 2002 disclose protocols for practicing some or all of the steps involved in identifying, detecting and quantifying proteins and protein fragments in tissue samples, body fluids and cell culture supernatants with antibodies that specifically bind epitopes through the use of signal emitting systems such as ELISA assays, western blots, immunohistochemistry, immunofluorescence, etc. (See the reference list submitted with this paper).

Applicant's arguments have been fully considered but are not found persuasive. The Examiner acknowledges that methods of detection of proteins, such as with ELISA assays and western blots, are well known in the art. However, the claimed method of detection is not enabled because Applicant has not provided any identifying characteristics for the GBP-1 fragments are detected in the supernatants. Although methods of detecting proteins are well known, the detection of proteins that have not been functionally or structurally characterized requires undue experimentation because one of skill in the art would not know how to recognize the GBP-1 fragments or how to detect GBP-1 fragments in the claimed method.

Furthermore, a large quantity of experimentation is required to generate the infinite number of GBP-1 derivatives recited in the claims, to determine which specific fragments of GBP-1 can be detected in a sample, as well as to identify the claimed receptors of the instant application would be required to detect them.

Claim Rejections - 35 USC § 112, Second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 and the newly added claims 16-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The basis of this rejection is set forth for claims 1-14 at page 11 of the previous Office action of 26 March 2007.

The rejection of claims 1-15 and the newly added claims 16-25 is maintained. Applicant's response and arguments filed on 10/26/2007 have been fully considered but they are not persuasive.

At page 21 of the response, Applicants direct to the disclosure in the specification at page 3, lines 11-17 and allege that this usage of "receptor" sufficiently defines the term.

Applicant's arguments have been fully considered but are not found persuasive. The specification does not provide a definition for receptor that is accepted in the art. In addition, the newly added claim 16 explicitly recites that the receptor is an antibody.

As disclosed at page 11 of the previous Office action (mailed 03/26/2007), here applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "receptor" in claims 1-25 is used by the claims to mean " antibody", while the accepted meaning of a receptor in the art is " a structural protein molecule on the cell surface or within the cytoplasm that binds to a specific factor " as recited in the Stedman's Medical Dictionary 27th edition (see attachment provided with the Office Action of 3/26/07). The term is indefinite because the specification does not clearly redefine the term.

New issues under *35 USC § 112, Second paragraph*

Claims 1-15 and the newly added claims 16-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-25 are rejected as being indefinite because claim 1 recites the limitation "a sample of the supernatant of a tissue culture", "a sample of the supernatant of a cell culture",

and “a sample of the supernatant of a body fluid in lines 5-6. There is insufficient antecedent basis for these limitations in the claim.

The term "labelling the proteins" in claim 2 is a relative term which renders the claim indefinite. The term "labeling the proteins" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For instance, it is not clear as to what proteins are labeled in the sample.

Claim 20 recites the limitation "tissue" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ian Dang whose telephone number is (571) 272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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